

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0104]

Display Date

DMB
3-28-02

Publication Date

3-29-02

Certifier

D. Hawkins

**Agency Information Collection Activities; Proposed Collection; Comment Request;
Consumer Handling of Ready-to-Eat Foods**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection that will occur during research to determine how consumers handle ready-to-eat (RTE) food products and how consumer practices impact the microbiological safety of RTE foods.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Consumer Handling of Ready-to-Eat Foods

Section 402 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342) authorizes FDA to regulate foods so that they are not adulterated. FDA’s research in food safety seeks to reduce the incidence of foodborne illness by improving the ability to find new ways to detect, enumerate, and control pathogens in the food supply. FDA’s Center for Food Safety and Applied Nutrition (CFSAN) awarded two grants of research funds in September 2001 to support research into consumer refrigeration practices and shelf-life for RTE foods entitled “Consumer Storage Length Practices for Ready-to-Eat Foods” and “Consumer Handling of Ready-to-Eat Foods After Purchase.”

The information that will be collected concerns consumer handling of RTE food products. The research will provide data on the storage of RTE foods in unopened and opened packages in home refrigerators; consumer understanding of expiration dates; and consumer use of this information in making decisions regarding purchases, consumption, and home storage conditions. The data from these surveys will be used to refine the Department of Health and Human Services and United States Department of Agriculture *Listeria monocytogenes* (LM) risk assessment, issued in draft for public comment on January 19, 2001 (66 FR 5515). The values used for home storage of foods in the draft LM risk assessment were largely based on expert opinion, not statistically supportable data. Thus, the consumer storage data from these two grants will improve FDA's confidence in the predicted risks by reducing the uncertainty in consumer practices.

For the "Consumer Storage Length Practices for Ready-to-Eat Foods," approximately 2,400 respondents will be selected from an already existing nationally representative web-enabled panel. For "Consumer Handling of Ready-to-Eat Foods After Purchase," a more traditional survey approach will be used and will be conducted in three parts. In part 1, approximately 400 in-person interviews will be conducted in Tennessee, Illinois, Kansas, Missouri, Florida, and New York. Participants will be selected to represent both sexes, different income groups and education levels, and a wide range of adults from different ethnic groups. In part 2, 100 respondents from part 1 will complete food diaries of specific foods from the day the food diary is initiated until those foods are consumed or discarded. In part 3, two mass mailings of questionnaires will be conducted one in fall-winter and the second in spring-summer for a total of 2,000 respondents.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN ¹

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Web-enabled panel survey	2,400	1	2,400	0.25	600
Interview survey	400	1	400	0.5	200
Food diary	100	1	100	0.5	50
Mail survey	2,000	1	2,000	0.3	600
Total					1,450

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of respondents given in table 1 is based on the study design in the two grant applications. The hours per response was estimated based on experience of the grantees for similar surveys and also on the number of questions to be included in each survey instrument.

Dated: 3/22/02
March 22, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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